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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,362	10/30/2003	Edward W. Merrill	37697-0081	6751

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EXAMINER
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BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,362

Applicant(s)

MERRILL ET AL.

Examiner

Susan W. Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8-1-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 124-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 124-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

The rejection of claims under 35 U.S.C. 112, first paragraph, is withdrawn.

The rejection of claims 124-127 under 35 U.S.C. 102(e) as being anticipated by Saum et al (6,316,158, filed 10-2-1996) is withdrawn. Applicant's amended claims clearly recite the MIR process disclosed in Application No. 08/600,744, filed 02/13/1996, before the effective filing date of US '158.

The finality of the rejection of the last Office action is withdrawn because the amendment to the claims obviates the rejection over Saum et al set forth therein.

New grounds of rejection are set forth herein below.

***Response to Amendment***

Applicant cites a decision in per *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) that analysis of changing numerical range limitations should take into account which ranges one skilled in the art would consider inherently supported by the discussion in the disclosure, Applicant also cites the decision in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ 2d 1481, 1487 (Fed. Cir. 2000) for support for carving out a patentably portion from a broad disclosure that did not clearly disclose a limitation to be part of a claimed invention. These citations are not persuasive with respect to the instant claims because the instant disclosure clearly sets forth several different variations of one method that generically comprises irradiation of a preform followed by melting of the irradiated preform (WIR-SM, CIR-SM, etc.) and a second method comprising melting a preform and subsequently irradiating the melted preform. Different conditions with respect to temperatures, radiation doses and times for

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irradiation, for instance, are clearly described for the different embodiments of the two basic processes and differ significantly for the MIR process and the IR-SM processes. There is no disclosure or suggestion that limitations from one embodiment are suitable for the other embodiment. Therefore, taking the limitations from one embodiment and setting these limitations forth in claims directed to the other embodiment is not considered to be supported by the disclosure as originally filed.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 126 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the MIR process disclosed in the specification the preform is irradiated with gamma radiation at a dose “greater than about 1.0 Mrad” or “greater than about 20 Mrads”. Applicant discloses irradiation at a dose **greater than 1.0 Mrad** or preferably **greater than 20 Mrad** in the disclosed melt-irradiation (MIR) process. The examiner has not found any supporting disclosure for the MIR process wherein the preform is irradiation at a “dose of about 1.0 Mrad to about 20 Mrad”, as now set forth in claim 126.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

It is noted that instant claims 124-126 are entitled to the 02-13-1996 filing date of US 5,879,400 because this parent patent discloses the method of melt irradiation (MIR). Instant claims 127-129 set forth the IR-SM processes first disclosed in SN 08/726,313, but not disclosed in US '400, while encompassing the MIR process disclosed in US '400,. Therefore, the effective filing date for instant claims 127-129 is considered to be 10-02-1996, the filing date of application SN 08/726,313, which discloses WIR-SM and CIR-SM methods.

Claims 124-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Dijkstra et al, in the article "Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation". Dijkstra et al disclose a process for crosslinking UHMWPE in the melt comprising heating a preform in a nitrogen atmosphere at 200 °C with electron

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beams. See "experimental" on page 866, Table 1. With respect to claims 127-129, Dijkstra et al anticipate the process set forth wherein the heating is performed before the irradiation.

Claims 127-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyon et al (6,168,626). Hyon et al disclose a method for producing UHMWPE for an artificial joint comprising irradiating UHMWPE with a low dose of radiation followed by compression-deformation after melting at a high temperature around the melting point and then cooling and solidifying. Table 2 appears to show that the samples treated according to the disclosed process have an increased tensile strength and an increased Young's modulus. With respect to claim 128, Hyon et al disclose temperatures around or not less than the melting point, preferably 160-220 °C (column 4, lines 4-16). Thus, claim 128 is anticipated by the teaching of Hyon et al to employ a temperature from the melting point minus 50°C to the melting point plus 80°C, which temperatures would be expected to be within the range of 137 to 300°C set forth in the claim. With respect to claim 129, Hyon et al teach a preferable dose 0.01 to 5.0 MR (column 3, lines 62-65). Thus the process disclosed by Hyon et al anticipates the process of instant claim 129 wherein the gamma radiation dose is about 0.5 to about 5.0 Mrad.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129, 131-134 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point to about 300<sup>0</sup>C and the time period is from about 5 minutes to about 3 hours or a time period of 5 minutes to about 24 hours and the polyethylene is UHMWPE. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. Thus the limitations of the process set forth in the instant claims are obvious variants of the limitations set forth in the claims of A.N. 10/197209.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-125, 130 and 143-146 of copending parent Application No. 09/764,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. The polyethylene recited in the claims of A.N. '445 encompasses the UHMWPE recited in the instant claims. Claims 124, 125 and 130 suggest instant claim 127. Claim 143 suggests instant claim 124. Thus species within the instant claims are obvious from the limitations set forth in the claims of A.N. 09/764,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**



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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB

8/19/05



Susan W Berman

Primary Examiner, AU 1711